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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.        | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------|------------------|
| 10/074,782   | 02/13/2002  | Peter DeChant        | VAL6131P0511US(WP<br>1646) | 7191             |
| 32116  | 7590        | 11/24/2004           | EXAMINER                   |                  |
| WOOD, PHILLIPS, KATZ, CLARK & MORTIMER<br>500 W. MADISON STREET<br>SUITE 3800<br>CHICAGO, IL 60661 |             |                      | SRIVASTAVA, KAILASH C      |                  |
|  |             |                      | ART UNIT                   | PAPER NUMBER     |
|  |             |                      | 1651                       |                  |

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

|                 |                           |              |                |
|-----------------|---------------------------|--------------|----------------|
| Application No. | 10/074,782                | Applicant(s) | DECHANT ET AL. |
| Examiner        | Dr. Kailash C. Srivastava | Art Unit     | 1651           |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 23 July 2004.  
2a) This action is FINAL.                    2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-36 is/are pending in the application.  
4a) Of the above claim(s) 1-22 and 36 is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 23-35 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
    1. Certified copies of the priority documents have been received.  
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
    Paper No(s)/Mail Date 23.07.2004.
- 4) Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

1. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 23 July, 2004 after a Final action mailed 30 January 2004. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the finality of the previous Office action mailed 30 January 2004 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submission filed on 23 July 2004 has been entered. Accordingly an RCE has been established and the action on RCE follows.
2. Applicant's responsive Amendment filed 23 July 2004 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.
3. In view of the remarks presented in Applicants' response filed 23 July, 2004 the rejection of Claims 22-34 under 35 U.S.C. § 112 first and second paragraphs for deposit requirement of *Bacillus sphaericus* strain 2362 and *Bacillus thuringiensis, var. israelensis* BT 1-17 in the Office action mailed 30 January 2004 is hereby withdrawn.

## **CLAIMS STATUS**

4. Claims 1-36 are pending.
5. Claims 1-22 and 36 stand withdrawn from consideration as being drawn to a non-elected invention. Examiner suggests that these non-elected claims be canceled in response to this Office action to expedite prosecution.
6. Claims 23-35 are examined on merits.

## **Objection To Specification**

7. Applicants should clearly define and delineate as to which wild type, isolated and biologically pure strains of *Bacillus sphaericus* and *Bacillus thurengiensis var. israelensis* as available to the public as commercial formulations under certain trademarks, i.e., VECTOBAC, VECTOLEX from Valent Biosciences Corp. At certain places in the specifications the products referred to *supra* are called VECTOBAC and VECTOLEX respectively (see, for e.g., Page 4, Line 30 to Page 5, Line 18). At other places, however, the name is VectoBac and VectoLex (See., e.g., Table 8, page 20, Lines 7-20). Furthermore, if the products are trademarks or trade names these products should be properly designated as trademark names (e.g., with a "™"). Appropriate correction/definition is required.

Examiner has not checked the entire specification to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicant may become aware in the specification. Applicants are cautioned to ensure that no new matter is added while correcting/defining those errors.

### ***Claim Rejections - 35 U.S.C. § 112***

8. In view of applicant's remarks filed 23 July 2004, following are new rejections to claims 23-35 under 35 U.S.C. §112 first paragraph.

9. Claims 23-35 are rejected under 35 U.S.C. § 112, first paragraph, because the claimed composition does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

From the record of the present written disclosure, the scope of the claimed invention recited in claims 23-35 is not supported by the specification on record and remarks made in applicants' response filed 23 July 2004, because in said specification working examples are drawn to a composition comprising a mixture of *Bacillus sphaericus* strain 2362 (i.e., ATCC Deposit Number SD-1170) and *Bacillus thurengiensis var. israelensis*. The specification does not define what strain of *Bacillus thurengiensis var. israelensis* was used in the experimental work (See for e.g., Page 4, Line 28 to Page 5, Line 7 or Page 17, Lines 9-24) because there is no mention of *Bacillus thurengiensis var. israelensis* BT 1-17 (i.e., ATCC Number SD-1276 according to Remarks files 23 July 2004) on record. Furthermore, applicants have exemplified only three preparations (See for e.g., Tables 1-2 and 5 and Examples 1, 2 and 5-6) for *Bacillus sphaericus* strain 2362 (i.e., "VECTOLEX CG, WDG and SPHERIMOS AS") and *Bacillus thurengiensis var. israelensis* (i.e., "VECTOBAC CG, WDG and AS12") without defining differences among said preparations of each of the organisms (See page 4, Line 28 to Page 5, Line 18). Consequently the invention cannot be construed to be drawn to any and every composition comprising a mixture of any and every *Bacillus sphaericus* with any and every *Bacillus thurengiensis var. israelensis*. Based on the description provided in the specification, a person of ordinary skill would not be able to practice the invention because undue experimentation will be required to practice the invention cited *supra*. Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to delineate that a mixture comprising any strain of *Bacillus sphaericus*, whether isolated from a natural source or genetically engineered with any strain of *Bacillus thurengiensis var. israelensis*, whether isolated from a natural source or genetically engineered; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth

of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

### ***Claims Rejections Under 35 U.S.C §103(a)***

10. Claims 23-35 stand rejected under 35 U.S.C. § 103 (a) as obvious over Rheaume et al. (U.S. Patent 5,560,909) in view of Meadows et al. (U.S. Patent 5,501,852) for reasons set forth in the Office Actions mailed 11 March 2003 and 30 January 2004 and additional reasons discussed below.

In response to the rejections made under item 16 of the Office Action mailed 11 March 2003 and under item 6 of the Office Action mailed 30 January 2004, applicants argue that the claimed invention is unobvious over the cited reference, because the cited reference do not disclose or suggest, or provide motivation to arrive at the presently claimed invention because the instantly claimed invention is on the unexpected discovery that the combination of both *Bacillus thuringiensis* subspecies *israelensis* and *Bacillus sphaericus* is effective in controlling dipteran larvae and inhibiting larvicidal resistance to known pesticides. Applicants further argue that the methods that Rheaume et al. and/or Meadows et al. teach to prepare their compositions comprising a mixture of *Bacillus thuringiensis* subspecies *israelensis* and *Bacillus sphaericus* are either ineffective, inferior or too expensive in contrast to the methods that the applicants have used in preparation of instantly claimed composition. Applicants also argue that Meadows et al. relate to controlling terrestrial lepidopteran insects/larvae in contrast to "an aquatic stage of a dipteran insect pest". In response to applicants' above-cited arguments, applicants' claims are not commensurate in scope with the claimed unexpected result or increased efficiency. Furthermore, the claims are drawn to a composition comprising *Bacillus thuringiensis* subspecies *israelensis* and *Bacillus sphaericus*; Consequently, regardless of the method of preparation of a given composition, the composition does not materially change. Moreover, the functional intended use of a composition does not materially change a composition and is accordingly, not given any patentable weight.

Applicant's arguments filed July 23, 2004 in regard to rejections made in the Office Action mailed 30 January have been fully considered but they are not persuasive. The rejection under 35 U.S.C. § 103(a) is adhered to for the reasons of record and the additional reasons discussed *supra*.

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons are cited under item 16 of the Office Action mailed 11 March 2003, under item 6 of the Office Action mailed January 30, 2004 and

discussion presented *supra*. Furthermore, a rejection under 35 U.S.C. § 103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

In response to applicants' arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

## ***CONCLUSION***

11. For aforementioned reasons no Claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 8:15 A.M. to 6:45 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571) 272-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*dk*  
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November 22, 2004